JUN 15 2012

510(k) Summary

Submitter: Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054

Contact Person: Kathleen Rutherford
Associate Director, Regulatory Affairs
Telephone: (973) 576-0139
Fax: (973) 884-8792

Date: June 6, 2012

Trade Name: TM-400 Device

Common Name: Intervertebral body fusion device & Spinal Vertebral Body Replacement Device

Classification Name: Intervertebral body fusion device, 21 CFR § 888.3080, Spinal intervertebral body fixation orthosis, 21 CFR § 888.3060

Device Panel/Product Code: Orthopedic MAX & MQP

Device Description:

The TM-400 Device is an oval shaped ALIF device for interbody fusion of the anterior column of the spine. The TM-400 Device is currently cleared to accommodate the replacement of a vertebral body in the thoracic and lumbar region of the spine. Use of this device is expanded to include use as an interbody fusion device. TM-400 Device is designed for fusing the adjacent bony surfaces and may be used to replace a disc at one or two contiguous levels in L2-S1. The device is available in a variety of cross sections and heights to accommodate variations in the individual pathology and anatomic condition of the patient. TM-400 implants are also available in two lordotic angles 7 degree and 13 degree. The superior and inferior surfaces of the device contain a pattern of teeth to provide for initial stability. The device also has slots to mate with the insertion instrument. The TM-400 device is wholly comprised of Trabecular Metal Porous Tantalum. Surgical instrumentation for use with the proposed system are fabricated from surgical grade stainless steel and other applicable materials.

Indications for Use:

The TM-400 device is a Vertebral Body Replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The TM-400 device is intended for use with supplemental internal fixation systems, and may be used with autograft or allograft.

The TM-400 device is also intended for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain with discogenic origin with degeneration of the

disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The TM-400 device is intended for use with supplemental internal fixation and autogenous bone graft.

Device Technological Characteristics and Comparison to Predicate Device(s):

The TM-400 Device was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include this TM-400 Device as a VBR (K052950, K031823, K010378 and, for the instrumentation, K093127), the Zimmer Spine, Inc. Ardis® Interbody System cleared under K073202, the Biomet Enclave cleared under K081636 and the Orthofix Pillar AL cleared under K082235.

The TM-400 Device has the identical material as previously cleared devices. The intended use and indications for use of the subject device are similar to those of its predicate devices. The sizes, design features and overall geometry of the device in the current submission are similar to the cleared predicate devices.

There are no significant differences between the TM-400 Device and the predicate devices currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy. The subject system is similar to its predicate devices with respect to intended use/indications for use, material, technological characteristics and basic principles of operation.

Performance Data:

Mechanical testing was performed on the TM-400 Device as recommended by the FDA *Class II Special Controls Guidance Document: Intervertebral Fusion Device*. The tests that were performed and the relevant ASTM Standards are as follows:

Mechanical Tests	**ASTM Standard**
Static Axial Compression	F2077-03
Dynamic Axial Compression	F2077-03
Static Torsion	F2077-01
Dynamic Torsion	F2077-01
Expulsion	N/R
Subsidence	F2267-04 & F2077

The results of testing and analyses conducted demonstrate that the proposed system adequately meets the predetermined requirements established for its mechanical performance.

Substantial Equivalence:

The TM-400 Device is substantially equivalent to its predicate devices with respect to intended use/indications for use, materials, technological characteristics and basic principles of operation as demonstrated by the supporting performance testing data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 15 2012

Zimmer Trabecular Metal Technology, Inc.
% Ms. Kathleen Rutherford
Associate Director, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K120203
Trade/Device Name: TM-400 Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: May 21, 2012
Received: May 29, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120203

Device Name: TM-400 Device

Indications for Use:

The TM-400 device is a Vertebral Body Replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The TM-400 device is intended for use with supplemental internal fixation systems, and may be used with autograft or allograft.

The TM-400 device is also intended for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The TM-400 device is intended for use with supplemental internal fixation and autogenous bone graft.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120203